Objection to the Applicant under 37 C.F.R. § 1.172(a)

At page 2 of the Office Action, this reissue application was objected to under 37 C.F.R. § 1.172(a) because it allegedly does not include the consent of all assignees of the patent. Applicant respectfully requests reconsideration of this objection.

U.S. Patent No. 6,239,118 (" '118 patent"), the reissue of which is the subject of this application, has not been assigned. Inasmuch as only assignees need to consent to the filing of a reissue patent application, if there are no assignees, no consent is needed. See M.P.E.P. § 1410.01:

> Where no assignee exists, applicant should affirmatively state that fact. This can be done by simply checking the "NO" box of item 7 of Form PTO/SB/50 (which form may be signed by the inventors, or by a registered practitioner). If the file record is silent as to the existence of an assignee, it will be presumed that *an assignee does exist*. This presumption should be set forth by the examiner in the first Office action alerting applicant to the requirement. It should be noted that the mere filing of a written assertion of small entity status in no way relieves applicant of the requirement to affirmatively state that no assignee exists.

(emphasis in original)

For at least the foregoing reasons, Applicant respectfully submits that the objection to the application under Rule 172(a) is simply in error as there is no assignee of the patent, the application is therefore not objectionable, and therefore respectfully requests withdrawal of the objection thereto.

Rejection under 35 U.S.C. § 112, first paragraph

In the Office Action, beginning at page 2, Claims 16 and 18 were rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matters that allegedly are not described in the specification in such a way as to convey to one skilled in the art that the inventors has possession of the claimed subject matter at the time of filing the application; that is, Claims 16 and 18 have been rejected as allegedly failing to satisfy the 'written description' requirement of Section 112. Applicant respectfully requests reconsideration of this rejection.

Patentability Standard: Written Description

A claimed invention may be unpatentable due to the lack of a written description if the specification fails to "clearly convey the information that an applicant has invented the subject matter which is claimed", *In re Barker* 559 F.2d 588, 592 (CCPA 1977), or if possession of what applicant claims as the invention is not put in the public domain. *See Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), *cert. denied,* 523 U.S. 1089 (1998). To satisfy the written description requirement, possession must be shown; however possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.,* 296 F.3d 1316, 1330 (Fed. Cir. 2002). For a claimed genus, the written description requirement may be satisfied through sufficient description of a representative number of species by disclosure of relevant identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of the above. *See Eli Lilly,* 119 F.3d at 1568. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *See* M.P.E.P § 2163, II, A, 3, a.

To adequately describe a claimed genus, a representative number of species encompassed by the genus must be implicitly or explicitly disclosed in the specification. To determine if a representative number of species is disclosed depends on whether one of skill in the art would recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed or claimed. Applicant respectfully submits that they were in possession of the necessary common attributes or features of the elements possessed by the members of the genus, and that such possession is evinced by applicants' specification.

Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81,

90 (Fed. Cir. 1986). If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the Written Description requirement is met. See, *e.g.*, *Vas-Cath*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (CCPA 1972) ("the description need not be in *ipsis verbis* to be sufficient").

The common attributes test for determining adequate written description of a claimed genus is clearly set forth in the Written Description Guidelines published in the Federal Register, Vol. 66, No. 4 on Friday, January 5, 2001("Guidelines for examination of patent applications under the 35 U.S.C. § 112 first paragraph "written description" requirement", 66 Fed. Reg. 1099, January 5, 2001); see also M.P.E.P. § 2163. As the Examiner is aware, the case law is clear that every species in a genus need not be described in order for a genus to meet the written description requirement. *See Eli Lilly*. Therefore, Applicants respectfully submit that a representative species, along with the other common attributes of the genus set forth in the specification and the knowledge in the art, is sufficient to adequately describe the claimed genus.

"Carrier" satisfies the Written Description requirement

The U.S. Patent and Trademark Office bears the initial burden of presenting evidence and reasoning why claimed subject matter may not satisfy the Written Description requirement of Section 112, after a full and thorough review of the entire application. *See* M.P.E.P. 2163, II, A. Applicant has, when first presenting Claims 16 and 18, identified specific passages in the '118 patent which expressly support the subject matter faulted in the rejection. *See Id.* The only justification offered in the Office Action for alleging that Claims 16 and 18 fail to satisfy the Written Description requirement stated:

> However, the specification does not disclose any carrier other than a stent (column 3, lines 20-21). One skilled in the art would not know what other carriers other than a stent would be included in the recitation "with a carrier."

(Office Action, page 2)

Applicant respectfully disagrees.

As correctly noted in the Office Action, Applicant has expressly, in the original disclosure, described both a genus ("carrier") and a representative species ("stent") of the claimed subject matter. The Office Action rightfully does not contend that Applicant did not have possession of the genus "carrier", because it had been recited in the specification to begin with, but instead somehow concludes, without the presentation of any evidence or reasoning, that Claim 16 nevertheless fails to satisfy the Written Description requirement.

Applicant has described in detail the administration to a human patient of at least one dose of a medicament, useful for preventing restenosis at a location of inflammation of the vasculature. One aspect of the invention includes administration of doses of the medicament intravenously and subcutaneously (see, *e.g.*, Claims 10 and 14), *i.e.*, systemically. Included in a genus of methodologies of systemic administration of the medicament are oral, subcutaneous, intravenous, intramuscular, and topical administration. See column 2, lines 22-26. As already acknowledged in the Office Action, an exemplary process of topical administration of the medicament is through the use of a carrier of that medicament, one exemplary species of which is by using a stent as a carrier of the medicament. It therefore appears that the Office Action's fundamental (and incorrect) assumption is that one of ordinary skill in the art of systemic administration of a medicament to a human patient, armed with the Applicant's disclosure that the medicament can be delivered on a carrier, *e.g.*, a stent, to the patient, would have no idea what other sort of 'carrier' could be used.

Applicant notes that the inquiry into what the skilled artisan would understand from Applicant's disclosure necessarily involves a threshold identification of the applicable art area. While the presently claimed subject matter involves a highly complex art dealing with a medicament useful for preventing restenosis in a patient's vasculature, it also involves a different art dealing with the systemic administration of a medicament to a patient. Without unnecessarily delving into a discussion of which art is more or less complex, and thus which art's skilled artisans are more or less skilled (see, *e.g.*, *Hybritech*, *supra*), Applicant fears that a biotechnology art standard has been applied to what is simply a medical device issue. Had the

Office Action presented the evidence and reasoning required in M.P.E.P. § 2163, Applicant would have a better opportunity to evaluate the issue of the level of skill in the art apparently alleged in the Office Action to be inadequate to understand what is a 'carrier' of a medicament.

The prior art, indeed the U.S. patent classification system, is rife with examples of medicament carriers, and thus is ample evidence that the subject matters of Claims 16 and 18 fully comply with the Written Description requirement of Section 112. By way of non-limiting examples, the U.S. Patent Classification System, Class 604, includes:

> subclass 890.1, simply entitled "Controlled Release Therapeutic Device or System", and thereunder subclass 892.1, "Osmotic or diffusion pumped device or system"; and
>
> subclass 502, "Therapeutic material introduced by subcutaneous implant (e.g., peritoneal injectors)".

A brief review of the contents of these and other analogous classes and subclasses in the U.S. Patent Classification System would quickly reveal that there are myriad medicament carriers with which the skilled artisan is well acquainted.

Turning now to the 'common attributes' inquiry, Applicants respectfully submit that a full and fair reading of the present application would easily inform the skilled artisan that a common attribute for the genus 'carriers', of which a stent is a representative and exemplary species, is simply the physical ability to 'carry' the medicament so that, when appropriately positioned in or on a patient, the medicament can be topically administered to the patient. While there could be other attributes that may be convenient or advantageous for specific applications, the term "carrier", along with the representative species of a stent, plainly conveys to the skilled artisan that the Applicants herein had full possession of the claimed invention, including the simple attribute of a "carrier" that it 'carry' medicament for topical administration.

For at least the foregoing reasons, Applicant respectfully submits that Claims 16 and 18 fully comply with 35 U.S.C. § 112, first paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

Conclusion

Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of this patent application is therefore respectfully solicited.

If Ms. Cook believes that a telephone conference with the undersigned would expedite passage of this patent application to issue, she is invited to call the undersigned at the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to Deposit Account 50-3100.

Respectfully submitted,

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Date: September 6, 2005